

FILED ELECTRONICALLY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appln. No. : 10/749,046 Confirmation No. 7407

Applicant : William J. Boyle et al.

Filed : December 29, 2003

Art Unit : 3762

Examiner : Moulton, Elizabeth Rose

Title : EMBOLIC PROTECTION DEVICES

Docket No.: : ACSES-66147 (G1738USC1)

Customer No. : 24201 December 9, 2009

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Dear Sir:

This Reply Brief is filed in response to the Examiner's Answer dated October 9, 2009. This Reply Brief is being filed within two (2) months of the date of the Examiner's Answer. In the event that fees are required, authorization is hereby provided to charge our Deposit Account No. 06-2425 any fees due in connection with this paper.

I. STATUS OF CLAIMS

The status of the claims in this application are:

A. Total Number of Claims in the Application

The pending claims in the application are: Claims 94-116.

Claims 1-93 have been canceled.

B. Status of All Claims on Appeal

Claims 94-116 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,152,946 to Broome et al. (the "Broome patent") in view of U.S. Patent No. 5,800,457 to Gelbfish (the "Gelbfish patent").

C. Claims on Appeals

The claims on appeal are each of pending claims 94-116.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

GROUND I

Whether independent claims 94, 101, 105 and 114, along with their dependent claims, were incorrectly rejected under 35 U.S.C. § 103(a) as being unpatentable over the Broome patent in view of the Gelbfish patent.

GROUND II

Whether dependent claims 115 and 116 were incorrectly rejected under 35 U.S.C. § 103(a) as being unpatentable over the Broome patent in view of the Gelbfish patent.

III. ARGUMENTS

GROUND I

The present invention is directed to a type of filtering device used to capture embolic debris entrained in the bloodstream of a blood vessel utilizing a filter element made from a flexible membrane. The flexible membrane must include a plurality of openings to allow at least some blood to flow therethrough while capturing embolic debris larger than the size of the openings. Debris is captured within a reservoir formed in the membrane. In use, the filter element is adapted to move from an expanded position to a collapsed position by sliding a restraining sheath initially over the **filter edge** and thereafter over the central region to move at least a portion of the filter element into the restraining sheath. The filter edge is configured similar to a crown, with a pattern of staggered alternation peaks and valleys that allow the **filter edge** to be incrementally introduced into the restraining sheath, thus preventing the filter membrane from entering the sheath all at once. Each valley region has a particular "depth" and each peak region has a particular "height" with at least two peak regions have different heights. As the filter

membrane is being retrieved, the longer peaks of the filter edge would enter the restraining sheath first and the shorter peaks would enter the sheath, accordingly, later to prevent bunching of the filter edge. Bunching of the filter member into the sheath can be problematic especially when the reservoir portion of the filter member is full with debris.

Appellant maintains that one skilled in the art would not consider combining the Broome patent with the Gelbfish patent in the fashion suggested by the Examiner. The Broome patent is directed to a filtering device which utilizes a filter membrane having an angulated filter edge but does not disclose, as admitted by the Examiner, a pattern of staggered alternation peaks and valleys that have differing "depths" and "heights" to allow the filter edge to be incrementally introduced into the restraining sheath.

The device disclosed in the Gelbfish patent, on the other hand, utilizes an expandable funnel shaped filter made from a solid web or film 166 (a "membrane") which is connected to a thrombectomy device which severs and removes pieces of debris from the funnel shaped filter body (See Column 11, lines 56-60 of the Gelbfish patent). The Gelbfish patent specifically teaches that a negative pressure source could be used to draw and remove debris collecting in a filter device prior to removal from the patient's vasculature.

The devices disclosed in the Broome patent and the Gelbfish patent are clearly distinct from one another and one skilled in the art viewing these patents would simply not consider combining them as the Examiner suggests. In the Gelbfish device, the membrane forming the funnel does not retain debris within a reservoir since the thrombectomy device is used to first cut and then remove all debris collecting in the funnel. Therefore, the problem associated with collapsing a full filter membrane by a restraining sheath is not addressed or even recognized in the Gelbfish patent. As such, one skilled in the art would recognize that the use of

a suction source, as disclosed in the Gelbfish patent, could be useful in emptying the contents of the Broome filter prior to removal of the device from the patient's anatomy.

Appellant submits that one skilled in the art, in reviewing both the Broome patent and the Gelbfish patent, would recognize that a vacuum source, as taught by Gelbfish, could be used to empty the filter device disclosed in the Broome patent prior to removing the Broome device from the patient's vasculature. The combination of these teachings from these particular references would be the correct application followed by one skilled in the art. Accordingly, the combination of components found in these two patents, as suggested by the Examiner, would not be correct.

Appellant submits that the Examiner has simply used the claims as a roadmap in hindsight reconstruction of the claimed invention utilizing these two patents. First, the Examiner found the Broome patent which does show a filter membrane having an angulated filter edge but fails to disclose, as admitted by the Examiner, a pattern of staggered alternation peaks and valleys that have differing "depths" and "heights" to allow the filter edge to be incrementally introduced into the restraining sheath. The Examiner supplements these shortcomings of the Broome patent by relying on the teachings of the Gelbfish which has no relevance to the type of filter disclosed in the Broome patent. The Examiner simply sought to locate any prior art filtering reference that utilizes a type of angulated structure having varying depths and heights. The Examiner was lucky enough to find such an articulating structure in the Gelbfish patent which utilizes an articulating **frame** having varying depths and heights to hold open the straight edge funnel made from a flexible membrane. However, the Examiner's combination of the Gelbfish device with the Broome device was made without regard as to whether such a combination of art would be a reasonable combination of art to one skilled in the

art at the time of the invention. Again, this is due to the fact that the devices disclosed in these two patents are so clearly distinct from each other.

Again it should be stated that the Gelbfish device does not teach the use of a filter member, as recited in the pending claims. The Gelbfish patent does not particularly describe how the funnel shaped filter body would be collapsed. However, as addressed above, the Gelbfish patent fails to recognize or appreciate the use of a membrane having a staggered edge having different heights and depths to prevent the membrane from entering the sheath in its entirety.

GROUND II

The Examiner has misinterpreted Appellant's position regarding claims 115 and 116. Appellant is not taking the position that the collar 28/34 cannot be both part of the frame and a collar, as stated by the Examiner. Appellant agrees that the collars 28/34 are part of the frame assembly. However, the frame assembly includes both collars and struts connected to each collar. Hence, a collar cannot be considered a strut, as the Examiner has concluded. Claim 116 requires the peaks of the filter element to be connected to a strut, not the collar of the frame assembly. The filter member in the Broome patent is attached to the collar 34, not a strut (rib 30). Moreover, the Examiner has taken an unreasonably broad interpretation of the word "attached." In the Broome patent, the filter element 40 is attached to the collar 36, not the struts 30. Given the Examiner's broad interpretation of the word "attached," it could be thus said that the filter element 40 would be attached to the physician's fingers every time the physician picks up the guide wire 32 upon which the filter device 20 is mounted. Appellant submits that the Examiner's interpretation of this word is far too broad.

IV. CONCLUSION

For all the reasons stated above, Appellant respectfully submits that the Examiner has erred in rejecting claims based on combination of the Broome

patent with the Gelbfish patent. It is respectfully requested that the Board reverse the rejection of the claims and allow claims 94-116 to pass to issue.

Respectfully submitted,

FULWIDER PATTON LLP

By: /Thomas H. Majcher/
Thomas H. Majcher
Registration No. 31,119

THM/lm